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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,267	08/20/2003	**Heather Lynn Davis**	C1040.70012US00	6263

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/644,267	DAVIS ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-53* is/are pending in the application.

4a) Of the above claim(s) *48-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/146,072.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/17/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed February 17, 2009 (hereinafter referred to as "the response") has been entered. No amendments have been made.

The elected invention is drawn to a method of inducing an antigen specific immune response in a subject by administration of an expression plasmid encoding a hepatitis B virus (HBV) antigen.

Claims 32-53 are pending in the instant application.

Claims 48-53 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention. Election was made **without** traverse in the reply filed on July 27, 2006.

Accordingly, Claims 32-47 are examined herein.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 17, 2009 has been entered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d

887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 32-47 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-14 of U.S. Patent No. 6,635,624. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the earlier-filed application are directed to a species that falls within the presently claimed genus. Thus, the claims of the patent anticipate the present claims (anticipation analysis).

At page 5 of the response, Applicants state that they may file a terminal disclaimer depending on the claims that are found to be allowable.

Accordingly, the rejection is maintained for reasons of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-47 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method as claimed, wherein the vector comprises a gene encoding a hepatitis B virus

surface antigen protein, and further wherein the vector comprises a promoter operably linked to the gene, such that the antigen is expressed in a vertebrate animal, does not reasonably provide enablement for the use of a vector encoding any other HBV antigen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are directed to a method of inducing an antigen-specific immune response in a subject by administration of an expression plasmid encoding a hepatitis B virus (HBV) antigen.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, are set forth in *In re Wands*, 8 USPQ2d 1400, at 1404 (CAFC 1988). These factors include: (1) the nature of the invention, (2) the state of the prior art, (3) the relative level of skill of those in the art, (4) the predictability of the art, (5) the breadth of the claims, (6) the amount of direction or guidance presented, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary.

Enablement has been evaluated giving due consideration to all the Wands factors, and the following factors are particularly noteworthy:

The state of the art of DNA vaccination is such that there are several significant limitations to the application of the methodology across different antigens. In an article published well after the filing date of the instant application, Rubanyi (2001) teaches that the problems described above remain unsolved at the time the instant application was filed. Rubanyi states, "[a]lthough the theoretical advantages of [human gene therapy] are undisputable, so far [human gene therapy] has not delivered the promised results: convincing clinical efficacy could not be demonstrated yet in most of the trials conducted so far …" (page 113, paragraph 1). Among the technical hurdles that Rubanyi teaches remain to be overcome are problems with gene expression control systems (see especially the section under "3. Technical hurdles to be overcome in the future", pages 116-125).

Beyond the technical barriers to all gene therapy approaches, each disease to be treated using gene therapy presents a unique set of challenges that must be addressed individually. The claimed methods encompass the use of a wide variety of genetic constructs to treat a wide variety of diseases. Rubanyi teaches, "each disease indication has its specific technical hurdles to overcome before gene therapy can become successful in the clinic (p. 131, paragraph 4). Rubanyi states, "the most promising areas for gene therapy today are hemophilias, for monogenic diseases, and cardiovascular disease (more specifically, therapeutic angiogenesis for myocardial ischemia and peripheral vascular disease…) among multigenic diseases" (p. 113, paragraph 4). As of the filing date of the instant application however, even the most promising areas presented barriers to successful gene therapy that could not be overcome by routine experimentation. Rather, the prior art shows that intensive investigation has met with limited success.

Route of administration: Haynes et al. (1996) further confirms the unpredictability for DNA vaccination across various routes of administration. The authors note the studies of Wolff and coworkers which demonstrated that direct muscle inoculation of plasmid DNA resulted in low level, sustained gene expression in rodent muscle. However, gene expression following muscle inoculation in nonhuman primate muscle was demonstrated at a significantly reduced efficiency (page 38, column 2, paragraph 2). The authors further refer to the advantage of gene gun-based DNA vaccine technology as being particularly useful in "larger animals where the potential for muscle injection is less clear" (page 38, column 2, paragraph 3). The unpredictability in the art of DNA vaccination also extends to the particular route of administration used. In describing the use of particle-mediated DNA immunization to produce protective immune responses in mice, the authors note that "[p]arallel immunizations via the intramuscular, intravenous, intraperitoneal, and intradermal routes, using considerably greater amounts of DNA, did not achieve comparable levels of vaccine protection." Thus, results obtained in mice by gene gun methods are not predictive of results obtained using other routes of administration. The authors go

on to report that "[a]dditional data comparing the relative efficacy of muscle injection and particle-mediated DNA immunization of the epidermis … demonstrated that considerably stronger immune responses could be elicited against several antigens using as little as 16 ng of DNA per immunization. Intramuscular injection of as much as 6000-fold more DNA did not achieve comparable immune responses" (page 39, paragraph bridging columns 1-2). Thus, the results obtained by gene gun methods are not predictive of results obtained by intramuscular administration. In 1993, the effective filing date of the instant application, methods of DNA vaccination were in their infancy and little was known about the consequences of different routes of delivery and the biological effects of different DNA delivery techniques.

In 1993, there were no clear guidelines for improving the *in vivo* expression of an antigen from a plasmid vector to achieve expression levels sufficient to produce a protective effect in large animals. Given the problems acknowledged by those skilled in the art, this is the epitome of unpredictability. The unpredictability of a particular art area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See *Ex parte Singh*, 17 USPQ2d 1714 (BPAI 1991). It is also well established in case law that the specification must teach those of skill in the art how to make and how to use the invention as broadly claimed. *In re Goodman,* 29 USPQ2d at 2013 (Fed. Cir. 1994), citing *In re Vaeck*, 20 USPQ2d at 1445 (Fed. Cir. 1991).

It is noted that the prior art generally acknowledges the critical role of the particular antigen used in DNA vaccination protocols. In a review of genetic immunization, Ertl et al. (1996, Viral Immunology, 9(1):1-9) emphasize the critical role of the antigen, stating that, "although any antigens can be delivered by genetic immunization, some proteins upon expression by plasmid vectors remain immunologically silent. The principles that govern success versus failure of genetic immunization with regard to each individual protein remain to be elucidated" (page 2, paragraph 3). This clearly indicates unpredictability in the art.

The court has recognized that physiological activity is unpredictable. *In re Fisher*, 166 USPQ 18 (CCPA 1970). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved. *In re Fisher*, 166 USPQ 18 (CCPA 1970).

It is not to be left up to the skilled artisan to figure out how to make the necessary starting materials and then to figure out how to use them to produce the biological effects as recited in the claims. The courts held that the disclosure of an application shall inform those skilled in the art how to use applicant's claimed invention, not how to **find out** how to use it for themselves. *In re Gardner et al.* 166 USPQ 138 (CCPA 1970). This specification only teaches what is intended to be done and how it is intended to work, but does not actually teach how to do that which is intended.

Given the unpredictability in the DNA vaccination and gene therapy art, and further given that the specification fails to provide specific guidance on which antigens (and genes encoding them) can be used to produce a protective immune response, across the very broad scope, the skilled artisan would have been required to engage in undue experimentation to develop a method within the scope of the claims for using any HBV antigen-encoding gene other than a gene encoding a surface antigen.

At page 6 of the response, Applicants assert that the claimed method involves administering to the subject a plasmid expression vector capable of expressing a hepatitis B virus antigen and including a promoter for the expression of the hepatitis B virus antigen in the subject in an effective amount to induce an antigen-specific immune response against a hepatitis B virus antigen. Applicants note that the specification teaches that the hepatitis B antigen may be a structural protein or a regulatory protein and that exemplary HBV antigens are disclosed in the specification and include HBV proteins and portions of proteins (i.e., fragments) such as HBV surface antigens and core antigens. Applicants further note that the specification discloses a series of exemplary expression vectors encoding HBV surface antigens and provides working examples evidencing that intramuscular injection of the expression vectors induces

antigen-specific immune responses in mice and in rabbits with antibody levels exceeding 10 mUI/ml, which is the threshold required to provide protection in humans. Applicants assert that the skilled artisan could readily produce expression vectors encoding immunogenic HBV antigens, using methods well known in the art, to perform the claimed methods.

At page 7 of the response, Applicants note that they now present published data demonstrating an antigen-specific immune response to DNA vaccination by intramuscular injection of plasmid expression vectors encoding additional HBV antigens (e.g., core antigens) and in multiple subjects to rebut any general teachings of unpredictability regarding the claimed invention.

At page 7, paragraph 2 of the response, Applicants go on to note, citing *In re Brana*, that post-filing data that follow the teachings of a disclosure to obtain a successful result, can be used as evidence in establishing that the disclosure was in fact enabling when filed. Applicants assert that, since the time the instant invention was filed, numerous reports have been published using the methods of the pending claims which demonstrate that intramuscular injection of plasmid expression vectors encoding HBV antigens (including surface and core antigens) induce specific immune responses in a variety of species, including mice, ducks, woodchucks, chimpanzees, and humans. Applicants further assert that a full range of immune responses have been described including humoral and cellular responses and protection against viral challenge (i.e., a protective immune response). Applicants submit 10 published reports and assert that each report uses the methods set forth in the instant invention and thus is evidence that the skilled artisan, following the methods of the disclosure could have practiced the claimed invention at the time of filing.

At page 7, paragraph 3 of the response, Applicants cite Lee et al. (2001) for demonstrating that intramuscular injection of mice with a plasmid expression vector encoding hepatitis B core antigens obtained from chronic active hepatitis patients results in a strong, specific antibody and cytotoxic lymphocyte response. However, the core antigen genes used were all mutant forms of the core antigen,

and while intramuscular administration of the W6 plasmid elicited a CTL response, as well as an antibody response, this gene has two point mutations (G25E and Q206R, page 16, column 1) that are not disclosed in the instant specification, and therefore the experiments of Lee et al. (2001) were not carried out in accordance with the teachings of the specification. Furthermore, the reference does not demonstrate that the antigen-specific response raised using the mutant core antigen gene (the combined CTL and antibody responses) correlates to a protective effect in the mice tested.

At page 7, paragraph 3 of the response, Applicants cite Kuhrober et al. (1997) for showing that intramuscular injection of plasmid expression vectors encoding hepatitis B core intracellular (HBcAg) and secreted (HbeAg) forms stimulate potent and specific antibody production and cytotoxic lymphocyte responses in mice. While the reference does disclose the detection of antibody and CTL responses, there is nothing in the reference to show that the immune response raised correlates to a protective effect and Applicants have not presented arguments tending to show that the immune response reported correlates to a protective effect.

At page 8, paragraph 1 of the response, Applicants note that, in woodchucks, woodchuck hepatitis virus (WHV) causes acute self-limiting and chronic infection similar to the effects of HBV in humans, and is accompanied by a specific humoral response to WHV surface and core antigens. Applicants cite Lu et al. (1999) for showing that intramuscular injection of woodchucks with a plasmid encoding either WHV surface or core antigens induces a specific immune response and controls subsequent WHV infection in challenge experiments. However, while WHV is used as a model system for acute and chronic hepatitis infection, WHV is distinct from HBV, with distinct sequences for the surface and core antigens and thus are not representative of immune responses that may be raised using plasmids that encode HBV antigens. Accordingly, the WHV experiments would not provide sufficient guidance for raising a protective immune response with plasmids encoding HBV core antigens. The references cited do not show a protective effect with plasmids encoding the HBV core antigens.

At page 8, paragraph 2 of the response, Applicants note that duck hepatitis B virus (DHBV) is closely related to HBV and has been used to study viral neutralization mechanisms in the Pekin duck. Applicants cite Triyatni et al. (1998) for showing that intramuscular injection of Pekin ducks with DNA vaccines coding for DHBV pre-S/S and S proteins results in the production of high titers of anti-DHBs antibodies and protects the ducks from subsequent viral challenge, as evidenced by clearance of DHBV inoculum from the bloodstream and reduction of DHBsAb in liver. In view of the post-filing evidence of Triyatni et al. (1998), the scope of enablement set forth above has been modified to embrace all vertebrates, rather than being limited to mammals, as set forth in the prior Office actions. The issue with regard to the unpredictability of DNA vaccination protocols across different species is withdrawn in view of the duck experiments and the chimpanzee experiments discussed below. With regard to the antigen, the Examiner has already acknowledged that the specification enables the use of a gene encoding an HBV surface antigen in the claimed method. The rejected scope of the claims is directed to antigens other than the HBV surface antigens, including the core antigens.

At page 8, paragraph 3 of the response, Applicants note that chimpanzees are similar to humans in their susceptibility to HBV infection and in the antibody titers required for protection. Applicants cite Davis et al. (1996) for showing that DNA vaccination of chimpanzees against HBV by intramuscular injection of plasmid expression vector encoding the small and middle HBV envelope proteins (HBsAg) induced a specific humoral response and helper T cell response, and produced antibody titers well above the critical protective level. Applicants further cite Prince et al. (1997) for showing that DNA vaccination of newborn chimpanzees by intramuscular injection of plasmid encoding HBV S and preS2 antigens induced a specific humoral response and protection against HBV challenge. The issue with regard to the unpredictability of DNA vaccination protocols across different species is withdrawn in view of the duck experiments discussed above and the chimpanzee experiments discussed here. With regard to the antigen, the Examiner has already acknowledged that the specification enables the use of a gene encoding an HBV

surface antigen in the claimed method. The rejected scope of the claims is directed to antigens other than the HBV surface antigens, including the core antigens.

At page 8, paragraph 4 of the response, Applicants cite Mancini-Bourgine et al. (2004) and Mancini-Bourgine et al. (2006) for reporting that phase I clinical trials in patients with chronic active viral hepatitis have revealed that intramuscular injections of a DNA vaccine encoding HBV surface antigens are well tolerated and induce specific T cell responses. Applicants note that these studies employed pCMV-S2.S (encoding HBsAg) which induces specific immune responses in both **mice** and **chimpanzees** (citing Michel et al. (1995) and Davis et al. (1996), respectively). Applicants conclude that this demonstrates the predictability of HBV antigens across subjects. As noted above, the issue with regard to the unpredictability of DNA vaccination protocols across different **species** is withdrawn in view of the duck and chimpanzee experiments discussed above. With regard to the antigen, the Examiner has already acknowledged that the specification enables the use of a gene encoding an HBV **surface** antigen (HBsAg) in the claimed method. The rejected scope of the claims is directed to antigens other than the HBV surface antigens, including the core antigens.

At page 9, paragraph 2 of the response, Applicants conclude, in summary, that the post-filing art cited demonstrates that, in accordance with the methods of the claimed invention and the teachings of the supporting specification, intramuscular injection of plasmid expression vectors encoding a range of HBV antigens, including both suface and core antigens, induce a protective immune response across a range of subjects. While it is agreed that the post-filing art demonstrates that intramuscular injection of plasmid vectors encoding an HBV **surface** antigen induces a protective immune response across a range of vertebrate subjects, for the reasons discussed above, there is no evidence that an expression vector encoding an HBV **core** antigen would induce a protective immune response in a subject.

Given the unpredictability in the DNA vaccination and gene therapy art, and further given that the specification fails to provide specific guidance on which antigens (and genes encoding them) can be used

to produce a protective immune response, across the very broad scope, the skilled artisan would have been required to engage in undue experimentation to develop a method within the scope of the claims for using any HBV antigen-encoding gene other than a gene encoding a **surface** antigen.

Conclusion

No claims are allowable.

This application contains claims 48-53 drawn to an invention nonelected without traverse in the reply filed on July 27, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

/Anne-Marie Falk/
Primary Examiner, Art Unit 1632